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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,750	02/19/2004	Joseph P. Vacanti	MIT 6917 (CMCC 450) DIV	5014
23579	7590	10/07/2009	EXAMINER	
Pabst Patent Group LLP 1545 PEACHTREE STREET NE SUITE 320 ATLANTA, GA 30309			GANESAN, SUBA	
			ART UNIT	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/782,750	<b>Applicant(s)</b> VACANTI ET AL.	
	<b>Examiner</b> SUBA GANESAN	<b>Art Unit</b> 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5,9,11-14,18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,9,11-14,18 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments with respect to claims 1-5, 9, 11-14 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-2, 4, 9, 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trudell et al. (U.S. Pat. No.: 5,207,705).
3. Trudell discloses a cell-matrix (abstract) construct for use as a valve leaflet (col. 7 lines 34-41 and col. 8 lines 40-43) comprising a fibrous polymeric matrix formed of biocompatible, biodegradable polymer (col. 5 lines 36-41) having endothelial cells (col. 7 lines 31-33 and col. 10 lines 58-62) seeded therein. The limitation "heart valve leaflet" is considered to be an intended use recitation; and the valve leaflet of Trudell is fully capable of serving the function of a heart valve leaflet, because the valve leaflet (col. 8 lines 40-43) regulates fluid flow and is biocompatible (col. 5 lines 61-67). The biodegradable polymer provides the biomechanical properties of a heart valve or leaflet, because the prosthesis can withstand repeated stress and strain (col. 10 lines 39-46).
4. Endothelial cells are considered dissociated connective tissue cells. The matrix is formed so that cells attach and proliferate thereon, (col. 7 lines 31-33 and col. 10 lines

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58-62), however, Trudell does not specifically disclose that the cells attach and proliferate to the edge of the matrix. However, since Trudell teaches cell proliferation on the matrix, and the edges of the matrix are the same composition as the bulk of the matrix, it is expected that cell proliferation would occur to the edge of the matrix.

5. The cell matrix construct includes degradable polyurethane (col. 5 lines 36-38). With respect to claim 11, Trudell does not specify that the material has 100-300 micron pores. However, it would have been obvious to provide such a pore size for the purpose of allowing cellular infiltration of the material. Trudell teaches that the base material is seeded with endothelial cells which grow to confluence. In order to facilitate such growth it is expected that the material of Trudell is within applicant's claimed porosity range. Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided 100-300 micron pores with the material of Trudell for the purpose of allowing cellular infiltration of the substrate. With respect to claim 12, the prosthesis includes growth factors (col. 7 line 22).

6. With respect to claim 14, Trudell discloses bioactive factors (col. 8 lines 58-69), but is silent as to the amount of the factor being between 1 and 30% by weight.

“[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It would have been obvious to determine the optimum amount of bioactive factor needed to produce a desired result in vivo; such a limitation is within the scope of routine experimentation. Therefore it would have been obvious to one of ordinary skill in the art to have used the

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disclosed bioactive factors of Trudell in an amount of 1-30% by weight for purpose of providing a treatment effective amount of bioactive factor. Trudell is silent as to the specific growth factor being one of the Markush listing of claim 13. However, it is submitted that these growth factors are well known in the art as a means to promote cell growth and attachment; it would have been obvious to one of ordinary skill in the art to utilize any of the specified list of growth factors as a matter of routine and obvious design choice when looking to improve the growth or attachment of cells.

7. Claims 3, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trudell et al. (U.S. Pat. No.: 5,207,705) in view of Sparks (U.S. Pat. No.: 3,514,791).

8. Trudell is explained supra. However, Trudell lacks implanting the matrix at a first site prior to being transplanted to a second site in the patient. The patient is considered to be an animal bioreactor.

9. Sparks teaches implanting a construct within a patient, allowing the construct to vascularize, and transplanting it at the desired implantation location (col. 2 lines 1-20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided this re-implantation technique with the device of Trudell for the purpose of improving the prosthetic's healing time and biocompatibility. Sparks teaches the use of the vascularization technique even with prosthetics seeded with cells. One of ordinary skill in the art, viewing the disclosure of Trudell and Sparks together, would have been motivated to provide the polymeric valve prosthetic of Trudell with an initial

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implantation and vascularization in a bioreactor (the patient) followed by a subsequent implantation in a desired location of implantation to improve the biocompatibility of the Trudell prosthesis. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the prosthetic valve of Trudell with an implantation in a first site prior to being transplanted in a second site as taught by Sparks. Such a modification would have occurred using known methods and would have yielded predictable results.

10. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trudell et al. (U.S. Pat. No.: 5,207,705) in view of Mikos et al. (U.S. Pat. No.: 5,514,378).

11. Trudell is explained supra. However, Trudell lacks seeding the prosthetic with endothelial cells and vascular smooth muscle cells. Mikos teaches seeding a membrane with endothelial cells and vascular smooth muscle cells (col. 14 lines 25+)

12. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided endothelial cells and smooth muscle cells on the prosthetic heart valve substrate of Trudell for the purpose of providing various extra-cellular matrix properties as a result of co-culturing two cell types. Such a modification would have occurred using known methods, and would have yielded predictable results.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. G./  
Examiner, Art Unit 3774

/DAVID ISABELLA/  
Supervisory Patent Examiner, Art Unit 3774